polyethylene. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification*. Class III.

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any shoulder joint metal/metal or metal/polymer constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a shoulder joint metal/metal or metal/polymer constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other shoulder joint metal/metal or metal/polymer constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50711, Sept. 27, 1996]

§ 888.3650 Shoulder joint metal/polymer non-constrained cemented prosthesis.

(a) *Identification*. A shoulder joint metal/polymer non-constrained cemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification*. Class II. The special controls for this device are:

(1) FDA's:

(i) ''Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' ''

(ii) ''510(k) Sterility Review Guidance of 2/12/90 (K90–1),''

(iii) ''Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement,''

(iv) ''Guidance Document for the Preparation of Premarket Notification (510(k)) Application for Orthopedic Devices,'' and

(v) ''Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components,''

(2) International Organization for Standardization's (ISO):

(i) ISO 5832–3:1996 ''Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-Aluminum 4-Vandium Alloy,''

(ii) ISO 5832–4:1996 ''Implants for Surgery—Metallic Materials—Part 4: Cobalt-Chromium-Molybdenum Casting Alloy,''

(iii) ISO 5832–12:1996 ''Implants for Surgery—Metallic Materials—Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy,''

(iv) ISO 5833:1992 ''Implants for Surgery—Acrylic Resin Cements,''

(v) ISO 5834–2:1998 ''Implants for Surgery—Ultra-high Molecular Weight Polyethylene—Part 2: Moulded Forms,''

(vi) ISO 6018:1987 ''Orthopaedic Implants—General Requirements for Marking, Packaging, and Labeling,'' and

(vii) ISO 9001:1994 ''Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing,'' and

(3) American Society for Testing and Materials':

(i) F 75–92 ''Specification for Cast Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implant Material,''

(ii) F 648–98 ''Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants,''

(iii) F 799–96 ''Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants,''

(iv) F 1044–95 ''Test Method for Shear Testing of Porous Metal Coatings,''

(v) F 1108–97 ''Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants,''

(vi) F 1147–95 ''Test Method for Tension Testing of Porous Metal Coatings,''

(vii) F 1378–97 ''Specification for Shoulder Prosthesis,'' and

(viii) F 1537–94 ''Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants.''

[52 FR 33702, Sept. 4, 1987, as amended at 65 FR 17148, Mar. 31, 2000]

§ 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* A shoulder joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) ''Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' ''

(ii) ''510(k) Sterility Review Guidance of 2/12/90 (K90–1),''

(iii) ''Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement,''

(iv) ''Guidance Document for the Preparation of Premarket Notification (510(k)) Application for Orthopedic Devices,'' and

(v) ''Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components,''

(2) International Organization for Standardization's (ISO):

(i) ISO 5832–3:1996 ''Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-aluminum 4-vandium Alloy,''

(ii) ISO 5832–4:1996 ''Implants for Surgery—Metallic Materials—Part 4: Cobalt-chromium-molybdenum casting alloy,''

(iii) ISO 5832–12:1996 ''Implants for Surgery—Metallic Materials—Part 12: Wrought Cobalt-chromium-molybdenum alloy,''

(iv) ISO 5833:1992 ''Implants for Surgery—Acrylic Resin Cements,''

(v) ISO 5834–2:1998 ''Implants for Surgery—Ultra-high Molecular Weight Polyethylene—Part 2: Moulded Forms,''

(vi) ISO 6018:1987 ''Orthopaedic Implants—General Requirements for Marking, Packaging, and Labeling,'' and

(vii) ISO 9001:1994 ''Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing,'' and

(3) American Society for Testing and Materials':

(i) F 75–92 ''Specification for Cast Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implant Material,''

(ii) F 648–98 ''Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants,''

(iii) F 799–96 ''Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants,''

(iv) F 1044–95 ''Test Method for Shear Testing of Porous Metal Coatings,''

(v) F 1108–97 ''Specification for Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants,''

(vi) F 1147–95 ''Test Method for Tension Testing of Porous Metal,''

(vii) F 1378–97 ''Standard Specification for Shoulder Prosthesis,'' and

(viii) F 1537–94 ''Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants.''

[52 FR 33702, Sept. 4, 1987, as amended at 65 FR 17148, Mar. 31, 2000]

§ 888.3670 Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis.

(a) *Identification.* A shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis is a device intended to be implanted to replace a